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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.:

DEX-0113

Inventors:

Yang et al.

Serial No.:

09/700,770

Filing Date:

January 16, 2001

Examiner:

Yaen, Christopher H.

Group Art Unit:

1642

Title:

A Novel Method of Diagnosing,

Monitoring, and Staging Lung Cancer

I, Kathleen A. Tyrrell, Registration No. 38,350, certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents P.O. Box 1450, Box IDS, Alexandria, VA 22313-1450

On this date: October 19, 2004

Kathleen A. Tyrrell, Registration No. 38,350

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

() In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

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application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- (XX) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
 - () Certification in Accordance with §1.97(e) is attached hereto; or
 - (XX) Authorization to charge Deposit Account No. 50-1619 the fee of \$180.00 as set forth in §1.17(p) is provided.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

() In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. ______, filed ______, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Kathleen A. Tyrrell

Date: October 19, 2004

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515

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List of Patents and Publications
Cited by Applicant
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	ва	6,331,427	12-18-01	Robison	435	226

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translat YES	ion NO
	вв	WO 00/61756	19-10-00	PCT	x	
	вс	WO 99/33869	8-7-99	PCT	x	
	BD	WO 98/45437	15-10-98	PCT	x	
	BE	WO 00/55180	21-9-00	PCT	x	_
	BF	WO 01/53486 A1	26-7-01	PCT	х	

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WO 99/63088

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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
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FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translat:	ion NO
	BL	WO 00/11168	2-3-00	PCT	х	
	вм	WO 98/13484	2-4-98	PCT	x	
	BN	WO 02/079398 A2	10-10-02	PCT	x	
	во	WO 00/01821	13-1-00	PCT	х	
	BP	WO 99/60160	25-11-99	PCT	х	

EXAMINER DATE CONSIDERED OT 2 1 2004

Form PTO-1449 Modified

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Applicant Sheet 04 of 14 Docket No. Serial No. DEX-0113 09/700,770 List of Patents and Publications Applicant (Use several sheets if necessary) Yang et al. U.S. Department of Commerce Filing Date Group January 16, 2001 1642 U. S. PATENT DOCUMENTS Examiner Document Date Name Class Subclass Initial No. FOREIGN PATENT DOCUMENTS Translation Examiner Document No. Date Country YES NO Initial WO 01/12659 A2 22-2-01 BQ PCT DATE CONSIDERED **EXAMINER**

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List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

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	Serial No.
DEX-0113	09/700,770

Applicant Yang et al.

Filing Date Group January 16, 2001 1642

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

OTHER DOC	OMEN.	is (including Author, i	itte, bate, reftiment rages, Etc./		
	CA	Athauda et al., "Structural Evidence for two Isozymic Forms and the Carbohydrate Attachment Site of Human Gastric Cathepsin E", Biochemical and Biophysical Research Communications 1990 168(2):878-885			
	СВ	Azuma et al., "Human Gastric Cathepsin E Gene", J. Biol. Chem. 1992 267(3):1609-1614			
	СС	Bin et al., "Identification of Uteroglobin-Related Protein 1 and Macrophage Scavenger Receptor with Collagenous Structure as a Lung Specific Ligand-Receptor Pair1", J. Immunology 2003 171:924-930			
	CD	Bingle et al., "PLUNC:A novel family of candidate host defence proteins expressed in the upper airways and nasopharynx", Human Molecular Genetics 2002 11(8):937-943			
	CE	Blundell et al., "The Aspartic Proteinases", Adv. Exp. Med. Biol. 1998 436:1-13			
	CF	Clark et al., "The Secreted Protein Discovery Initiative (SPDI), a Large-Scale Effort to Identify Novel Human Secreted and Transmembrane Proteins:A Bioinformatics Assessment", Genome Research 2203 13:2265-2270			
	CG	Cook et al., "Pronapsin A and B gene expression in normal and malignant human lung and mononuclear blood cells", Biochimica et Biophysica Acta 2002 1557 10-16			
	СН	Couvreur et al., "Assignment of cathepsin E (CTSE) to human chromosome region 1q31 by in situ hybridization and analysis of somatic cell hybrids", Cytogenet Cell Genet 1990 53:137-139			
	CI	Doorbar et al., "The El^ E4 Protein of Human Papillomavirus Type 16 Associates with a Putative RNA Helicase through Sequences in Its C Terminus", J. Virology 2000 74(21): 10081-10095			
EXAMINER			DATE CONSIDERED		

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Form PTO-1449 Modified

List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

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Docket No. DEX-0113	Serial No. 09/700,770
Applicant	

Applicant Yang et al.

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OTHER	DOCUMENTS	(Including	Author,	Title,	Date,	Pertinent	Pages,	Etc.))
-------	-----------	------------	---------	--------	-------	-----------	--------	-------	---

CJ	Koelsch et al., "Multiple functions of pro-parts of aspartic proteinase zymogens", FEBS Letters 1994 343:6-10
CK	Krop et al., "HIN-1, a putative cytokine highly expressed in normal but not cancerous mammary epithelial cells", Proc. Natl. Acad. Sci. USA 2001 98(17):9796-9801
CL	Niimi et al., "UGRP1, a Uteroglobin/Clara Cell Secretory Protein-Related Protein, Is a Novel Lung-Enriched Downstream Target Gene for the T/EBP/NKX2.1 Homeodomain Transcription Factor", Molecular Endocrinology 2001 15(11):2021-2036
СМ	Niimi et al., "A Polymorphism in the Human <i>UGRP1</i> Gene Promoter That Regulates Transcription Is Associated with an Increased Risk of Asthma", Am. J. Hum. Genet. 2002 70:718-725
CN	Niimi et al., "Cloning, expression, and chromosomal localization of the mouse gene (Scgb3al, alias Ugrp2) that encodes a member of the novel uteroglobin-related protein gene family", Cyotogenet Genome Res 2002 97:120-127
СО	Kimura et al., "The <i>T/ebp</i> null mouse: thyroid-specific enhancer-binding protein is essential for the organogenesis of the thyroid, lung, ventral forebrain, and pituitary", Genes & Development 1996 10:60-69
CP	Mori et al., "Molecular cloning of a novel mouse aspartic protease-like protein that is expressed abundantly in the kidney", FEBS Letters 1997 401:218-222
CQ	Schauer-Vukasinovic et al., "Cloning, expression and functional characterization of rat napsin", Biochimica et Biophysica Acta 2000 1492:207-210
CR	Shibata et al., "Disruption of structural and functional integrity of α_2 -macroglobulin by cathepsin E", Eur. J. Biochem. 2003 270:1189-1198

EXAMINER

DATE CONSIDERED

Form PTO-1449 Modified

EXAMINER

List of Patents and Publications Cited by Applicant (Use several sheets if necessary)

U.S. Department of Commerce

Docket No.	Serial No.
DEX-0113	09/700,770
Applicant	

Applicant Yang et al.

Filing Date Group January 16, 2001 1642

OTHER DOC	UMEN	S (Including Author, Title, Date, Pertinent Pages, Etc.)
	CS	Strausberg et al., "Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences", Proc. Natl. Acad. Sci. USA 2002 99(26):16899-16903
	CT	Takenaka et al., "Isolation of genes identified in mouse renal proximal tubule by comparing different gene expression profiles", Kidney International 1998 53:562-572
	CU	Tatnell et al., "An alternatively spliced variant of cathepsin E in human gastric adenocarcinoma cells", Biochimica et Biophysica Acta 2003 1625:203-206
}	CV	Tatnell et al., "Molecular organization, expression and chromosomal localization of the mouse pronapsin gene", European Journal of Biochemistry 2000 267(23):6921-6931
	CW	Wattiez et al., "Human bronchoalveolar lavage fluid protein two-dimensional database:Study of interstitial lung diseases", Electrophoresis 2000 21:2703-2712
	CX	Zhang et al., "Identification of Tissue-Specific Genes in Nasopharyngeal Epithelial Tissue and Differentially Expressed Genes in Nasopharyngeal Carcinoma by Suppression Subtractive Hybridization and cDNA Microarray", Genes, Chromosomes & Cancer 2003 38:80-90
	CY	NCBI Genbank Accession No. Q920H1 [gi:20140641] 1 March 2002 with Revision History
	CZ	NCBI Genbank Accession No. Q96PL1 [gi:20140698] 1 March 2002 with Revision History
	DA	NCBI Genbank Accession No. Q920D7 [gi:20140640] 1 March 2002 with Revision History

DATE CONSIDERED

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List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce

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DEX-0113	03/100,110
<u> </u>	

Applicant Yang et al.

OTHER DO	CUMEN	TS (Including Author,	Title, Date,	Pertinent Pages, Etc.)		
	DB NCBI Genbank Accession No. Q96QR1 [gi:20140699] 1 March 2002 with Revision History					
	DC	NCBI Genbank Accession No. AY040564 [gi:15079187] 2 August 2001 - 15 August 2001 with Revision History				
	DD NCBI Genbank Accession No. BC029176 [gi:20809672] 16 May 2002 with Revision History					
	DE NCBI Genbank Accession No. AF086152 [gi:3483497] 29 August 1998 with Revision History					
	DF		CBI Genbank Accession No. AF436839 [gi:33315289] 9 September 2003 with Revision History			
	DG	NCBI Genbank Accession No. AY359064 [gi:37183245] 1 October 2003 with Revision History				
	DH	NCBI Genbank Accession No. NM_052863 [gi:16418366] 25 October 2001 - 23 March 2002 with Revision History				
	DI	NCBI Genbank Accession No. AC005794 [gi:3702272] 6 October 1998 with Revision History				
	DJ NCBI Genbank Accession No. NP_571785 [gi:18858489] 20 February 2002 with Revision History					
EXAMINER			DATE CONSID	ERED		

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OTHER DOO	UMEN:	IS (Including Author, I	Litle, Date,	Pertinent Pages,	Etc.)	
	DK NCBI Genbank Accession No. NP_001900 [gi:4503143] 19 March 1999 - 15 April 2002 with Revision History					
	DL	NCBI Genbank Accessio 2 May 2001 with Revis		58 [gi:13928928]		
	DM NCBI Genbank Accession No. BAA90785 [gi:6978973] 15 February 2000 with Revision History					
	DN NCBI Genbank Accession No. BAB22158 [gi:12832561] 8 February 2001 - 26 December 2001 with Revision History				.story	
	DO		CBI Genbank Accession No. NP_032463 [gi:6680552] January 2000 - 7 January 2002 with Revision History			
	DP NCBI Genbank Accession No. AAF17080 [gi:6561816] 12 December 1999 with Revision History					
	DQ	NCBI Genbank Accession No. NP_004842 [gi:4758754] 7 May 1999 18 - December 2001 with Revision History				
	DR	NCBI Genbank Accession No. AAH17842 [gi:17389633] 6 December 2001 with Revision History				
	DS	NCBI Genbank Accession 1 March 1992 - 1 Marc				
EXAMINER			DATE CONSIDE	RED		

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List of Patents and Publications
Cited by Applicant
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Applicant Yang et al.

OTHER DO	OCUMEN'	TS (Including Author, Title, Date, Pertinent Pages, Etc.)		
•	DT	NCBI Genbank Accession No. 009043 [gi:6016430] 15 July 1999 - 1 March 2002 with Revision History		
	DU NCBI Genbank Accession No. 096009 [gi:6225749] 15 December 1999 - 16 October 2001 with Revision History			
	DV NCBI Genbank Accession No. NM_016355 [gi:10047107] 9 September 2000 - 21 August 2001 with Revision History			
	DW NCBI Genbank Accession No. NM_001910 [gi:4503144] 19 March 1999 - 18 September 2002 with Revision History			
	DX NCBI Genbank Accession No. NP_652013 [gi:21355083] 8 June 2002 with Revision History			
	DY NCBI Genbank Accession No. NM_148964 [gi:23110951] 18 September 2002 with Revision History			
	DZ	NCBI Genbank Accession No. BC017842 [gi:17389632] 6 December 2001 with Revision History		
	EA NCBI Genbank Accession No. AF098484 [gi:4235424] 8 February 1999 with Revision History			
	EB	NCBI Genbank Accession No. AF090386 [gi:4154286] 14 January 1999 with Revision History		
EXAMINER		DATE CONSIDERED		

OT 2 1 2004 E

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List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce

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Applicant Yang et al.	

OTHER DO	CUMEN	TS (Including Author, Title, Date, Pertinent Pages, Etc.)			
•	EC NCBI Genbank Accession No. AF200345 [gi:6561817] 12 December 1999 with Revision History				
	ED	ED NCBI Genbank Accession No. BC040958 [gi:27155062] 17 December 2002 with Revision History			
	EE NCBI Genbank Accession No. AAP36305 [gi:30584113] 13 May 2003 with Revision History				
	EF NCBI Genbank Accession No. P24268 [gi:115720] 1 December 1992 - 20 August 2001 with Revision History				
	EG NCBI Genbank Accession No. AAL25709 [gi:16551119] 31 October 2001 with Revision History				
	EH NCBI Genbank Accession No. NP_473379 [gi:16905071] 12 November 2001 with Revision History				
	EI	NCBI Genbank Accession No. AAL25708 [gi:16551117] 31 October 2001 with Revision History			
	EJ	NCBI Genbank Accession No. AAQ04562 [gi:33316004] 19 September 2003 with Revision History			
	EK NCBI Genbank Accession No. NP_473364 [gi:16876445] 9 November 2001 with Revision History				
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Applicant Yang et al.

OTHER DO	OCUMENT	S (Including Author, Title, Date, Pertinent Pages, Etc.)			
	EL	NCBI Genbank Accession No. Q96PL1 [gi:20140698] 1 March 2002 with Revision History			
	ЕМ	NCBI Genbank Accession No. Q920H1 [gi:20140641] 1 March 2002 with Revision History			
	EN	NCBI Genbank Accession No. AF364078 [gi:19880273] 2 April 2002 with Revision History			
	EO	NCBI Genbank Accession No. AY358595 [gi:37182311] 1 October 2003 with Revision History			
	EP	NCBI Genbank Accession No. BC008429 [gi:14250057] 30 May 2001 with Revision History			
	EQ	NCBI Genbank Accession No. AK127971 [gi:34535114] 9 September 2003 with Revision History			
	ER	ER NCBI Genbank Accession No. NM_004851 [gi:4758753] 7 May 1999 - 22 August 2001 with Revision History			
	ES NCBI Genbank Accession No. NM_033197 [gi:15082247] 4 August 2001 with Revision History				
	ET	NCBI Genbank Accession No. AY58433 [gi:37181990] 1 October 2003 with Revision History			
EXAMINE	R	DATE CONSIDERED			

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	U.S. Department of Commerce		Filing Date January 16, 2001	Group 1642	
OTHER DOO	UMEN'	TS (Including Author,	Title, Date, Perti	nent Pages, Etc.)	
-	EU NCBI Genbank Accession No. XM_209141 [gi:27485250] 3 January 2003 with Revision History				
	EV NCBI Genbank Accession No. NM_198477 [gi:38348269] 15 November 2003 with Revision History				
	EW	NCBI Genbank Accession No. NM_054023 [gi:16876444] 9 November 2001 with Revision History			
	EX	NCBI Genbank Accession No. AY358979 [gi:37183075] 1 October 2003 with Revision History			
·	EY NCBI Genbank Accession No. AF439545 [gi:33315997] 19 September 2003 with Revision History				
	EZ NCBI Genbank Accession No. BC024232 [gi:18999381] 28 February 2002 with Revision History				
	FA	NCBI Genbank Accession No. AF313455 [gi:16565415] 1 November 2001 with Revision History			
	FB	NCBI Genbank Accession No. AC011497 [gi:6015255] 7 October 1999 - 14 July 2002 with Revision History The Revision History for 8844110 which replaces 6015255 is provided			
	FC NCBI Genbank Accession No. AL356798 [gi:8217849] 24 May 2000 - 26 September 2001 with Revision History - The Revision History for 15795413 which replaces 8217849 is provided				

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OTHER DOCUMENTS (Including Author,	Title, Date, Perti	nent Pages, Etc.)		
	NCBI Genbank Accession No. BF335657 [gi:11306405] 11 November 2000 with Revision History			
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EXAMINER DATE CONSIDERED				